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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,096	11/24/1999	BERNARD ACKERMAN	ACKRAD-5	5859

7590 03/07/2002

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EXAMINER

SERKE, CATHERINE

ART UNIT PAPER NUMBER

3763

DATE MAILED: 03/07/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/449,096

Applicant(s)

ACKERMAN, BERNARD

Examiner

Catherine Serke

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the method provides for the fabrication of the same exact catheter as specified in claim 9. This is not found persuasive because only one-way distinctness needs to be met to satisfy the restriction requirement. As noted in the previous correspondence, the catheter or product can be made by another process than the one claimed in the instant invention. Not only can the formation of the openings in the catheter tube be made during the extrusion process but additionally the balloon and the tube together could be manufactured as a monolithic structure not requiring the "attaching a balloon" step. Clearly, the requirements for a restriction have been properly met and therefore the requirement is made final.

Claims 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ackerman in view of Valtchev.

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Ackerman discloses a catheter with a tubular body having two lumens with openings respectively. A polyurethane balloon is disposed on the distal end of the device and is in communication with one lumen opening. The second lumen and opening communicate with the exterior of the device to dispense a diagnostic fluid into the uterus. The body of the catheter is flexible and has a moveable sheath disposed thereon. As shown in figures 4A and 4B the balloon can be inflated into first and second predetermined shapes.

Ackerman meets the claim limitations as described above but fails to disclose a lumen having an opening for communication with the uterus and a second opening for communication with the interior of the balloon.

Valtchev discloses a single channel balloon uterine injector that includes a catheter body with a balloon on the distal end for injection of dye or contrast medium into a uterine cavity. Figure 7 clearly shows an embodiment that includes a lumen extending through the body of the catheter tube with openings at the distal end for communication with the interior of the uterus. Additionally, the lumen has an opening for communicating with the balloon for inflation of the balloon.

At the time of the invention, it would have been obvious to incorporate the teachings of Valtchev regarding the single lumen for inflation and injection into the invention of Ackerman. The two references being for insertion and injection into the uterus are analogous in the art and therefore a combination is proper. Additionally, motivation for the combination can be found in the disclosure of Valtchev (see 1:60+). The Valtchev device is specifically designed to provide a uterine injector that is simpler to use. By incorporating the single lumen into the invention of

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Ackerman, the combined device eliminates the need to have the medical technician manipulate both an inflation syringe and another medical device.

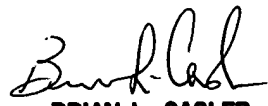
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine Serke whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke 
March 5, 2002


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700